REMARKS

Applicants wish to thank the Examiner for the review of the present application. Claims 1, 7, 10, 15, 18-22, 55-61, 66-71, 85-86 and 94-153, 190, and 228-256 are now pending in the application and stand rejected. Applicants have amended claims 1, 10, 153, and 190. No new matter has been added.

INTERVIEW SUMMARY

The Applicants also thank the Examiners for the courtesy of the Interview held on December 3, 2009. The Interview was held at the United States Patent Office and was attended by Examiner Jonathan G. Cwern and Supervisory Patent Examiner Brian Casler on behalf of the Patent Office and by Alex Smolenski, David Cerveny, Dr. Philipp Lang, M.D., M.B.A., and Dr. Daniel Steines, M.D., Ph.D. on behalf of the Applicants. During the Interview, the parties discussed the cited Ateshian references and Applicants' belief that the cited reference are not enabling as to how a patient specific prosthesis can be generated. Applicants indicated that, among other things, U.S. Patent 6,126,690 (Ateshian '690) cannot be enabling, because, as discussed in more detail below, approximately one year after that patent was filed, Ateshian expressly noted in subsequently filed United States Patent 6,161,080 (Ateshian '080) that the claimed invention did not yet exist. That statement in the later-filed Ateshian '080 application constitutes an express admission by Ateshian that, at the time the Ateshian '690 patent was filed, Ateshian could not have possessed the invention claimed by the Applicants. The Examiners indicated that, prior to the Interview, they had themselves discussed other potential problems with citing Ateshian '690 as an enabling reference, but reserved making a determination until they had an opportunity to review Applicants' response. The parties also discussed adding new claims to further specify applicant's invention, and more clearly differentiate the claims from the the cited references.

35 U.S.C. § 102

Claims 1, 7, 10, 15, 153 and 190 stand rejected under 35 U.S.C §102(e) as being

anticipated by Ateshian et al. (US 6,126,690) (Ateshian '690), which was filed on July 3, 1996.

Claim 1 of the present application is directed to a method of creating an implant for treating joint disease comprising determining at least a portion of the geometry of an implant by obtaining information about the three-dimensional geometry of the joint, wherein the information includes information on the thickness or shape of at least one of articular cartilage, including normal and/or diseased articular cartilage, and subchondral bone and creating an implant based on the three-dimensional geometry of the joint, wherein at least a portion of said implant has an outer surface based on the derived information. However, consistent with the discussions in the Interview on December 3, 2009 and the arguments below, each of independent claims 1, 10, 153 and 190 have been amended to clarify that a patient-specific bone electronic and/or computerized model of at least a portion of a patient's joint is used in each of the claimed methods. The Applicants have disclosed the use of such models at great length and in great detail throughout the specification.

Ateshian '690 does not disclose such methods, either as previously claimed or as amended. Ateshian '690 discloses a joint prosthesis for attachment to a bone of a patient, comprising an anchor with a head surface and a stem for attachment to an end of the bone, the head surface having an anatomically accurate shape. The office action states that Atheshian discloses that image data of a healthy joint can be obtained and used to fabricate a prosthesis for a similar diseased joint (column 6, lines 20-32). However this is quite different from the embodiment disclosed Applicant's method of creating an implant for an actual damaged or diseased joint. Applicant's method obtains information about the three-dimensional geometry of the joint, including thickness or shape of at least one of articular cartilage (normal and/or diseased) and subchondral bone and creates an implant using information from the image of the actual joint where the implant is to be implanted. Ateshian looks at a joint in good condition and compares the information with a database of mathematical descriptions of a plurality of articular joint surface archetypes to determine which one exhibits the smallest deviation from the imaged data of the undamaged joint. Ateshian then fabricates a prostheses to resemble the archetype which exhibits the smallest deviation from the imaged data (of an undamaged joint).

In short, almost the entire disclosure of Ateshian '690 is nearly entirely directed to using other people's bones to create a more functional bone surface. In other words, Ateshian '690 discloses a method that is not patient-specific. Ateshian '690 discloses how to make a "best-fit" prosthesis based on an image of an undamaged joint and a database of mathematical descriptions of archetypes. In contrast, Applicants claim the use of information on thickness and shape obtained from the image of the actual diseased or damaged joint, to create an implant for implantation into the damaged or diseased joint.

Ateshian '690 Does Not Enable the Creation of Patient-Specific Implants With MRI or CT Scans

Although, as discussed above, Ateshian '690 primarily discloses a very different invention than claimed by the Applicants here, the Office Action cites to some very limited and cursory disclosure for the proposition that Ateshian '690 discloses the creation of patient-specific implants from a patient's own MRI or CT scans. (Ateshian '690, Col. 7, lines 20-39.) The relevant portion of that citation states:

> According to another aspect of the present invention a method of manufacturing a joint prosthesis for a patient's bone is provided, comprising obtaining imaging data of the joint surface of the patient's bone, modifying the imaged data of the joint surface of the patient's bone to provide a more functional surface topography, fabricating a replicate of the modified imaged data to provide a functional joint prosthesis.
>
> The step of fabricating may further comprise the step of combining a plurality of modular head and stem sections.
>
> The step of obtaining imaging data of the joint surface of the patient's bone may comprise magnetic resonance imaging. The step of obtaining imaging data of the joint surface of the patient's bone may comprise computed tomography.

Despite this cursory statement in Ateshian '690, there is no further written description in support of such an embodiment. Everything that Ateshian otherwise describes to enable the invention is essentially directed "disarticulating" bones, mounting the "specimen, photographing the specimen, denuding the specimen of cartilage using acid, and photographing the specimen

again. The photography is performed using a stereographic camera external to the body as shown in FIG. 1. There is no detailed description or other written description to support the statement above. On its face, Ateshian '690 has not provided sufficient information to practice this so-called "aspect" of that invention.

In fact, in a later-filed patent, Ateshian actually notes that such technology was not available. The Ateshian '080 patent was filed approximately 16 months after the Ateshian '690 patent. At Col. 38, lines 7-14, the later-filed Ateshian '080 expressly notes that, *in the future*, it may be possible to use CT or MRI imaging modalities to obtain imaging data directly from a patient to create a patient specific model of the joint. Specifically, Ateshian '680 states:

> With improving non-invasive in vivo imaging technologies such as CT and MRI, it ***may be possible*** to obtain geometric data needed for the model directly from patients. Already several investigators have reconstructed cartilage topography and thickness from MR images. Once the patient joint geometry is obtained, a patient specific model can be constructed and analyzed to suggest a best physical therapy program or a surgical procedure.

(Emphasis added.) This express statement by Ateshian that improvements in imaging technology may one day make it possible to create patient-specific models of a patient's joint, also stands expressly for the corollary proposition that it was not yet possible to do so at the time Ateshian '080 was filed. In other words, Ateshian could not have reduced such an invention to practice either at the time of the '080 patent or 16 months earlier when the '690 patent was filed. Thus, contrary to the cursory disclosure of the Ateshian '690 patent, Ateshian's own words demonstrate that he did not have the ability to obtain images from a live patient and to create a patient-specific model or implant from that imaging data did not exist even 16 months after the Ateshian '690 patent was filed. Thus, it is impossible for Ateshian to have enabled that "aspect" of his invention when the Ateshian '690 patent was filed. Although the Applicants do not believe that the additional limitation is required to distinguish the claims over Ateshian, they have amended the claims to clearly show that a patient specific electronic model is used in the creation of the

patient-specific implants, which is the precise element that Ateshian indicates was not possible at the time of the '080 and '690 patents.

Note also that far more credence should be given to Ateshian's statement in the later-filed Ateshian '080 patent that it was not yet possible to create a patient-specific electronic model than to the disclosure of the Ateshian '690 patent. The Ateshian '080 patent is directed to, and contains significant disclosure of, computer modeling of joints in the related field of surgical planning. As such, Ateshian '080 contains a large amount of detailed disclosure related to such electronic modeling. In contrast, similar disclosure is not present in the Ateshian '690 patent. Thus, there is no evidence in the Ateshian '690 patent, that Ateshian had undertaken the patient-specific computer modeling work needed to enable to presently claimed invention or to reduce to practice the patient-specific "aspect" of the Ateshian '690 disclosure. Instead, Ateshian's primary and only detailed embodiment disclosed at that earlier point in time was the external stereographic imaging of denuded bones extracted from bodies. When the Ateshian '080 and '690 patents are compared side-by-side, the obvious implication is that, while Ateshian may initially have believed that creating a patient-specific joint from a patient's own imaging data was a simple proposition, he apparently later discovered, after he began doing detailed work with computer models in the related field of surgical-planning, that it was not as easy as he originally thought, indeed not yet possible at all according to his own statement.

Thus, while Ateshian may originally have thought that he enabled that aspect of his invention in the '690 patent, his own later statements show that he had not.

35 U.S.C. §103(a)

Claims 10, 15, 18-19, 21-22, 55-58, 60-61, 66-71, 85-86, 94-152, and 228-256 stand rejected as being unpatentable over U.S. Patent No. 6,126,690 (Ateshian et al.) in view of U.S. Patent Number 6,161,080 (Aouni-Ateshian et al.), U.S. Patent No. 5,682,886 (Delp et al.), U.S. Patent No. 5,320,102 (Paul et al., hereinafter "Paul") and U.S. Patent No. 6,835,377 (Goldberg et al., hereinafter "Goldberg"). Claims 20 and 59 similarly stand rejected as unpatentable over these

same references in further view of U.S. Patent No. 6,175,655 (George, III et al., hereinafter "George, III")

Collectively, the references cited by the Examiner disclose methods of medical imaging, modeling joints and treating cartilage. However, none of the references – either alone or in combination – discloses obtaining image data of a joint and generating a patient-specific device having an articular surface that is based on the information from the image data. Specifically, all of the independent claims in this application recite devices in which an outer, articular surface of the device is derived from image data of a joint. In claim 1, the outer surface is created based on information concerning cartilage or subchondral bone that is obtained from the image data. In claim 10, the outer surface is created based on information concerning cartilage that is obtained from the image data. In claims 153 and 190, the outer surfaces are formed or created based on information about the underlying subchondral bone of the joint.

None of the art cited by the Examiner discloses these features of the claims. Delp, for example, primarily discloses a surgical planning system that can be used with existing implants to plan surgeries or assist in robotic surgeries. Delp, however, does not disclose a system that can be used to create implants or physical models based on the image data that is used. In fact, Delp explicitly states that the implants used in conjunction with the surgical planning methods are those that are commercially available, and further states that the structure of these implants are not important.

> It is intended that the invention can be used with any commercially-available prosthesis, whether standard or custom-designed, and ***the structure of the prosthesis is not important*** except that data representing its size and configuration must be loaded into the planning software in order to provide accurate sizing and placement information and useful planning information.

(See Delp, col. 12, lines 47-61 (emphasis added).) Thus, not only does Delp not disclose the methods of forming and creating implants and physical models as claimed, Delp actually teaches away from such concepts by explicitly stating that the structure of such devices are not important.

Similarly, Ateshian '080 employs images of joints, but does not specifically disclose any

particular type of implant that is designed. Instead, Ateshian primarily discloses using image data to create virtual models of joints. With regard to designing prostheses, Ateshian discloses only that "[p]rostheses and other medical instruments may be more efficiently designed and evaluated using a model." (See col. 1, lines 62-64.) Ateshian fails to disclose any detail about the structure of such prostheses. More specifically, Ateshian fails to disclose or suggest that an implant or physical model may be created or formed with an outer surface based on the geometry of a particular joint. Further, as noted above, Ateshian actually states that generating patient-specific computer models may be possible in the future, clearly implying that Ateshian did not enable such an invention at the time of filing.

Goldberg also fails to disclose the methods as claimed, and, instead, discloses very different technology. Goldberg is directed to the regeneration of cartilage using, for example, "a suspension of purified fibrillar collagen or modified collagen and culture-expanded human mesenchymal stem cells (hMSCs)." (Goldberg Col. 5, lines 48-50.) Goldberg states in the abstract that the invention is "[f]or repair of cartilage damaged as part of the degenerative effects of osteoarthritis" and that "the inventors have found that the human mesenchymal stem cell approach makes it possible to [among other things] regenerate both shallow cartilage chondral defects and full thickness cartilage defects…" Golberg does not disclose implants or physical models as claimed. Thus, nothing in Goldberg would cause one skilled in the art to combine the references with any other references to obtain the claimed inventions.

Paul similarly fails to disclose all of the claimed elements of the independent claims. As noted in the abstract, Paul uses MRI images to diagnose proteoglycan deficiency in articular cartilage. Paul does not disclose any implants or physical models, as those concepts are absent from the specification. More specifically, Paul does not teach or suggest all of the elements of the claims, and nothing in Paul would cause one skilled in the art to combine that reference with others to create the claimed methods.

Finally, as with the other cited art, George, III does not teach or suggest the claimed methods, and nothing in that reference would cause one skilled in the art to combine that reference with others to create the claimed methods. George, III discloses methods of generating and manipulating three-dimensional images from MRIs and other medical images, but does not

disclose the creation for formation of implants and physical models using those images. Thus, George does not teach or suggest the independent claims.

Claims 7, 15, 18-22, 55-61, 66-71, 85-86 and 94-152 are each patentable for at least the same reasons, because they depend from independent claims 1 and 10. Thus, all of the pending claims in the application are patentable over each or, and every combination of, Delp, Ateshian, Goldberg, Paul, and George, III.

CONCLUSION

All pending claims are believed to be in a form suitable for allowance. Therefore, the application is believed to be in a condition for allowance. The Applicants respectfully request early allowance of the application. The Applicants also request that the Examiner contact the undersigned, if it will assist further examination of this application.

Applicants believe that a three month extension of time is required, and hereby request that the associated fees be charged to Deposit Account No. 19-4972. Applicants also request that any other fee required for timely consideration of this application be charged to Deposit Account No. 19-4972.

DATE: April 23, 2010

Respectfully submitted,

/Alexander J. Smolenski, Jr., #47,953/

Alexander J. Smolenski, Jr.
Registration No. 47,953

Sunstein, Kann, Murphy & Timbers, LLP
125 Summer Street
Boston, MA 02110-1618
617-443-9292

03104/00109 1254377.1